K112645 P1/3.

SEP 2 2 2011

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Date 5/30/2011

510(k) Summary (in accordance with 21 CFR 807.92)

1. Date of Summary

5/30/2011

2. Company

EIZO GmbH
Siemensallee 84
D-76187 Karlsruhe, Germany

3. Authorized Contact Person

Guenter Michael Volz

4. Device Information

- Trade Name/Model: RadiForce Large Monitor System
- Common Name: RadiForce Large Monitor System
- Classification Name: Display, Cathode-Ray Tube, Medical
- Classification Number: 21 CFR 870.2450, Product Code DXJ

5. Predicate Device

- Cardio-View (K083321)

6. Device Description

The system consists of the following components:

- LS560W Large Monitor – Model No. 6GF6200-8A$## – mandatory component
- LMM56800 Large Monitor Manager – Model No. 6GF6020-1A$## – mandatory component
- PDC0100 Analog DVI Converter – Model No. 6GF6010-0B$## – optional accessory
- PDS0800 DVI Splitter/Scaler – Model No. 6GF6020-0AA00-#$$# – optional accessory
- TDL3600 Transmission Link – Model No. 6GF6010-#$$## – optional accessory
- CID1000P Control Interface Device – 6GF6550-2H$## – optional accessory
- Cabinet – optional accessory

where "$" signifies a letter from A to Z, and "#" a number from 0 to 9.

The RadiForce Large Monitor System is a large color flat panel monitor for viewing images derived from several video sources on a single display and to rearrange these images to the situational requirements of the user. To appreciate all of the advantages of the large widescreen monitor, the data has to be collected from the various sources and prepared for variable viewing. This is handled by the mandatory "Large Monitor Manager" ("LMM"). In some reports or references you will find the "LMM" being called "MDM" for "Multi Display Manager" (customer specific product name). The various video sources are being bundled using the Large Monitor Manager and from there being fed into the Large Display via two DVI lines.
Control of the video sources can also be accomplished using Eizo's Control Interface Device CID as optional part of the system or any other standard browser compatible operator console.

7. Intended Use

The RadiForce Large Monitor System is intended to be used by health care professionals to integrate the video output from various commercially available instruments commonly used in a medical procedure laboratory into a single video display.

8. Technological Characteristics

The RadiForce Large Monitor System uses a color LCD panel employing Multi-domain Vertical Alignment (MVA) technology to allow wide viewing angles. It has a resolution of 3840 x 2160 pixels and is used in landscape mode.
The various video sources from medical and other devices are being collected using the Large Monitor Manager and from there being fed into the Large Display via two DVI lines. An optional external operator console (Control Interface Device CID) can be used as optional part of the system to rearrange pictures from the regarding sources or switch between numerous presets according to specific user's needs.

The RadiForce Large Monitor System may be offered in different housing colors and with different logos. These are cosmetic differences and of no effect on the function and performance of the system.

Regarding the comparison of the intended use of the two large monitor systems both address the benefit of image integration and management.
It enables the clinician to fully customize captured image sources and their arrangement due to the specific situational needs. Switching between different layouts and thus reprioritizing the images takes only milliseconds.

The overall design of the display and the Large Monitor Manager processor were validated in accordance with internationally recognized safety and EMC standards by independent testing facilities.
EIZO GmbH performed a range of system and performance tests to ensure that the RadiForce Large Monitor System performed in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance of a large color flat panel display system.

As with the predicate device, the RadiForce Large Monitor System was designed to receive and display images from standard, commercial DVI and analog display controllers.

9. Performance Testing

The RadiForce Large Monitor was successfully tested to comply with NEMA's PS 3.14 DICOM standard (Grayscale Standard Display Function).
Though there is no precise pass/fail criterion present within the DICOM standard, we consider the compliance to be excellent because of the very close proximity of the measured values towards the ideal curve represented by the Barten model.

A system test was conducted successfully on the RadiForce Large Monitor System, including MDM/LMM, Large Monitor, FPGA + Bootsoftware + Firmware, photometers SSM and ASLM.

Moreover, each component of the system has been certified seperately and as a working unit (Large Monitor System) according to following standards:

Large Monitor, Transmission Link and CID:	IEC 60601-1
CID and Converterbox:	IEC 60950-1
MDM/LMM and Splitter:	UL 60950-1
Large Monitor System:	IEC 60601-1-1
CID, Converterbox and Large Monitor	IEC 60601-1-2
Large Monitor System:	FCC Part 15, subpart B
Large Monitor System:	IEC 60601-1-2, radiated emissions only

Thus the electrical safety and electromagnetic compatibility of the system and its components could be verified by third party laboratories.

10. Conclusions

The RadiForce Large Monitor System is substantially equivalent to the predicate device with respect to technical characteristics, application and intended use. All functions of the Radiforce Large Monitor System are identical to the predicate device. Any differences between the devices do not affect safety or effectiveness.

The 510(k) Pre-Market Notification for the RadiForce Large Monitor System contains sufficient information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

EIZO GmbH
c/o Mr. Bhavesh V. Sheth
Intertek Testing Services NA, Inc.
2307 E Aurora Rd. Unit B7
Twinsburg, OH 44087

SEP 22 2011

Re: K112645
Trade/Device Name: RadiForce Large Monitor System
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II (two)
Product Codes: DXJ
Dated: September 3, 2011
Received: September 12, 2011

Dear Mr. Sheth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112645

Device Name: RadiForce Large Monitor System

Indications For Use: The RadiForce Large Monitor System is intended to be used by health care professionals to integrate the video output from various commercially-available instruments commonly used in a medical procedure laboratory into a single video display.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112645